

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GEORGE PIECZENIK,

Plaintiff,

v.

ASTELLAS PHARMA, INC., et al.,

Defendants.

Civil Action No. 10-02253 (FLW)(TJB)

Motion Return Date: July 6, 2010

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**BRIEF OF DEFENDANTS KYOWA HAKKO KIRIN AMERICA, INC. AND
KYOWA HAKKO KIRIN PHARMA, INC.
IN SUPPORT OF THEIR MOTION TO DISMISS**

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INTRODUCTION

Defendants Kyowa Hakko Kirin America, Inc. and Kyowa Hikko Kirin Pharma, Inc. (collectively, “the Kyowa Hakko Kirin defendants”) respectfully submit this opening memorandum in support of their motion to dismiss the complaint filed by *pro se* plaintiff, George Pieczenik, on May 5, 2010.

Dr. Pieczenik’s complaint is styled as a “Complaint For Patent Infringement And Racketeer Influence and Corrupt Organization (RICO) And Jury Demand.” That complaint sets forth a series of allegations against the Kyowa Hakko Kirin defendants -- in addition to 14 other named parties (and unnamed “John Does 1 through 61”) -- that are largely incomprehensible. As the Kyowa Hakko Kirin defendants explain below, Dr. Pieczenik’s complaint is inconsistent with the requirements of Rule 12, Fed. R. Civ. P because:

- A. to the extent that Dr. Pieczenik intended to charge the Kyowa Hakko Kirin defendants with infringement of U.S. Patent 5,866,363 (“the ‘363 patent”), Dr. Pieczenik has not identified any product made, used, sold, offered for sale or imported by the Kyowa Hakko Kirin defendants (or any method that they employ) that could possibly meet the limitations of any claim of the ‘363 patent;
- B. to the extent that Dr. Pieczenik intended to charge the Kyowa Hakko Kirin defendants with a violation of the RICO statute, Dr. Pieczenik does not set forth any factual allegations that the Kyowa Hakko Kirin defendants have engaged in any of the statutorily-defined “racketeering activities,” which is a required element of any RICO claim; and
- C. to the extent that Dr. Pieczenik’s assertion that “the claims

in defendant's patents" are "substantially similar to claims in plaintiff's patent" and are, therefore, "invalid" can be interpreted as a claim for declaratory judgment that patents owned by the Kyowa Hakko Kirin defendants are somehow invalid, that claim must fail because: (1) the Kyowa Hakko Kirin defendants have never threatened Dr. Pieczenik with a patent infringement suit and, therefore, no case or controversy exists; and (2) in any event, Dr. Pieczenik does not even identify any particular patent owned by the Kyowa Hakko Kirin defendants that could possibly be at issue here.

Accordingly, the plain words of the complaint filed by Dr. Pieczenik confirm that he has no basis whatsoever to assert *any* cause of action against the Kyowa Hakko Kirin defendants. Indeed, it appears that Dr. Pieczenik's complaint against the Kyowa Hakko Kirin defendants is simply the latest in a long line of lawsuits alleging patent infringement and RICO violations that Dr. Pieczenik has brought against dozens of parties in different district courts. The Kyowa Hakko Kirin defendants understand that no court has ever found any of those claims to have merit.

Rule 12(b)(6), Fed. R. Civ. P., provides that "failure to state a claim upon which relief can be granted" is an appropriate ground to dismiss all or part of a pleading. Likewise, Rule 12(b)(1), Fed. R. Civ. P. authorizes a District Court to dismiss a claim for "lack of subject matter jurisdiction." This Court has not hesitated to grant motions brought under Rule 12 to eliminate defective claims. *See Die Casters Int'l v. United States*, 2009 U.S. Dist. LEXIS 90541 (D.N.J. Sept. 29, 2009); *Watford v. Union County College*, No. 06-cv-5542, 2009 U.S. Dist. LEXIS 9661, at *5 (D.N.J. Feb. 10, 2009).

In accordance with Rule 12(b)(6) and 12(b)(1), Fed. R. Civ. P., therefore, the Kyowa Hakko Kirin defendants respectfully request that Dr. Pieczenik's complaint be dismissed in its entirety.

DR. PIECZENIK'S LITIGATION CONDUCT CONFIRMS THAT THERE IS NO BASIS FOR HIS PRESENT CLAIMS

Between May 3 and May 7, 2010, Dr. Pieczenik filed with this Court four separate, but virtually identical, complaints against more than 100 companies (including the Kyowa Hakko Kirin defendants) and 61 "John Does." As the Kyowa Hakko Kirin defendants explain herein, there is absolutely no basis for Dr. Pieczenik's claims against them and, indeed, it appears that Dr. Pieczenik failed to conduct any pre-suit investigation as is required by Rule 11, Fed. R. Civ. P. *See, e.g., View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000).

Dr. Pieczenik has previously engaged in this same type of blunderbuss litigation in which he accused dozens of parties of patent infringement (including infringement of the '363 patent) and RICO violations. In connection with Dr. Pieczenik's infringement allegations, the United States District Court for the District of Massachusetts and the United States Court of Appeals for the Federal Circuit have construed the claims of the '363 patent very narrowly. On two different occasions, both the Massachusetts Court and the Federal Circuit rejected Dr. Pieczenik's

allegations of infringement of the '363 patent against Dyax Corp. -- whom Dr. Pieczenik has sued *yet again on the same patent here*. (Exs. A-D).¹

The United States District Court for the Southern District of New York also rejected Dr. Pieczenik's infringement allegations against dozens of parties directed to a "continuation" of the '363 patent. (Ex. E, Docket No. 32).² The claims of the continuation patent that Dr. Pieczenik asserted in the New York litigation included the very same limitations that the Massachusetts Court and the Federal Circuit considered and disposed of in the earlier Dyax case. (Exs. G-I).

In the New York case, Dr. Pieczenik also accused numerous parties of RICO violations.³ In deciding that case, Judge Scheindlin characterized Dr. Pieczenik's RICO allegations as follows:

The PTO and the FDA are alleged to have engaged in numerous unlawful conspiracies. *First*, the FDA conspired with Bristol-Myers, and Merck AG ("Merck") to "manipulate the price of Genetic Systems and Imclone stock [to] take control of their respective monoclonal antibodies used for cancer treatment and remove the Jewish scientists and founders from their respective corporations." *Second*, the FDA and the PTO colluded with the Department of Justice ("DOJ") to "ignore the fact that they are

¹ As used herein, "Ex. __" refers to the identified exhibit to the Declaration of Jordan S. Adler, Esq., which is submitted concurrently herewith.

² A "continuation" patent has the identical specification of the parent application -- in this case, the application that issued as the '363 patent.

³ In the course of the New York litigation, Dr. Pieczenik also sued the Commissioner of the United States Food and Drug Administration, the Commissioner of Patents, the Medical Research Council of Great Britain, Nobel Laureates (*e.g.*, Joshua Lederberg and Sir Aaron Klug), large pharmaceutical companies (including Pfizer and Bristol Myers Squibb) and 61 "John Does."

dealing and accepting filings and patents from a pharmaceutical company, Merck [], that has never been de-nazified and, therefore, is still a criminal enterprise unto itself.” *Third*, the FDA and the PTO, along with Bristol-Myers, Merck, and unnamed defendants, have created: (1) “‘free patent zones’ as policy to allow foreign corporations and US pharmaceutical companies to ‘walk over’ individual American inventor patent rights in violation of the American Inventors Protection Act”; (2) “a non importation embargo of patent drugs from Canada in violation of [Pieczenik’s] patent rights”; and (3) “a monopoly trust in violation of [Pieczenik’s] patent rights.” *Fourth*, the PTO engaged in wire fraud through its communications with Medical Research Council-Laboratory of Molecular Biology, CAT, Dyax Corp., and Domantis (Ex. F at 6-7).

Not surprisingly, the New York Court promptly dismissed Dr. Pieczenik’s RICO claims *with prejudice* (Ex. E, Docket No. 32).⁴

To the extent that Dr. Pieczenik’s present RICO charge is premised on the same allegations (which simply cannot be ascertained from Dr. Pieczenik’s May 5, 2010 complaint) that charge also is barred under the principles of *res judicata* and collateral estoppel. *United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 173 (3d Cir. 2009); *Temple Univ. v. White*, 941 F.2d 201, 212 (3d Cir. 1991).

⁴ On November 24, 2003, the presiding judge -- Hon. Shira A. Scheindlin -- issued an Order as follows: “Dr. Pieczenik is hereby directed to refrain from telephoning my Chambers. All future communications from Dr. Pieczenik must be in writing with copies to all adversaries.” (Ex. E, Docket No. 41). Ultimately, the New York Court did not find in favor of Dr. Pieczenik on any of his claims. And, the Federal Circuit ruled against Dr. Pieczenik on appeal. (Ex. E, Docket No. 103).

LEGAL ARGUMENT

POINT I

DR. PIECZENIK'S COMPLAINT FAILS TO STATE A CLAIM OF PATENT INFRINGEMENT

A. Dr. Pieczenik Does Not Set Forth an Actionable Charge of Direct Infringement

Dr. Pieczenik's complaint sets forth vague and unsupported allegations that the Kyowa Hakko Kirin defendants -- as well as the 14 other parties named in the complaint (and the 61 unnamed "John Does") -- somehow infringe the '363 patent because:

- "By virtue of defendant's research, commercial and licensing activities, defendants have infringed upon plaintiff's patent and have contributed to others infringing on plaintiff's patent" (D.I. 1 at ¶ 27)
- and
- the defendants as "corporations and individuals allow for a situation where their management, scientists and sales personnel 1) infringe on the '363 patent, 2) create companies which infringe the '363 patent and 3) collaborate with companies which infringe on the '363 patent."⁵ (D.I. 1 at ¶ 29)

Rule 8(a)(2), Fed. R. Civ. P., requires a plaintiff to set forth in its complaint a "short and plain statement of the claim showing that the pleader is entitled to relief." As the United States Supreme Court explained, "detailed factual allegations" are not required, but the Rule does call for sufficient factual matter, accepted as true, to "state

⁵ The Kyowa Hakko Kirin defendants understand that Dr. Pieczenik has filed three additional complaints with this Court presenting virtually identical allegations against over 80 other named defendants and the 61 "John Does."

a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). The United States Supreme Court has also made plain that “[a] court considering a motion to dismiss may begin by identifying allegations that, because they are mere conclusions, are not entitled to the assumption of truth.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1940 (2009).

Here, Dr. Pieczenik fails to support his conclusory assertions of patent infringement with any factual allegations at all. When considering the question of whether a plaintiff has sufficiently set forth a claim of patent infringement, courts will typically look for an allegation that the defendant infringes either by making, using, selling, offering for sale or importing a product or method that embodies a patent claim. See *Sharafabadi v. Pac. Nw. Farmers Coop*, No. 09-cv-1043, 2010 U.S. Dist. LEXIS 2936, at *5-6 (W.D. Wash. Jan. 14, 2010); *Eidos Commc’ns, LLC v. Skype Techs., SA*, No. 09-cv-234, 2010 U.S. Dist. LEXIS 16224, at *5 (D. Del. Feb. 24, 2010); see also 35 U.S.C. § 271(a); Fed. R. Civ. P. Appx., Form 18. Courts require specificity in the identification of the allegedly infringing product or method. See *Bender v. LG Elecs. U.S.A., Inc.*, No. 09-cv-02114, 2010 U.S. Dist. LEXIS 33075, at *11-12 (N.D. Cal. Mar. 11, 2010); *Bender v. Motorola Inc.*, No. C 09-1245, BA, 2010 WL 726739, at *3 (N.D. Cal. Feb. 26, 2010).

In his May 5, 2010 complaint, Dr. Pieczenik fails to identify anything at all that the Kyowa Hakko Kirin defendants have done that could possibly have formed the basis of an infringement charge. The Kyowa Hakko Kirin defendants are unaware of

any product that they make, use, offer for sale, sell or import (or any process that they employ) that bears any relationship to the claims of the ‘363 patent. Indeed, one of the parties -- Kyowa Hakko Kirin America, Inc. -- is simply a holding company.

B. Dr. Pieczenik Does Not Set Forth an Actionable Charge of Indirect Infringement

Dr. Pieczenik also makes an imprecise assertion in his complaint that defendants have “contributed to” infringement by others. The concept of “contributory infringement” is governed by 35 U.S.C. § 271(c), which provides that a party is liable for infringement if he “offers to sell or sells within the United States or imports into the United States ... a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.”

Dr. Pieczenik’s complaint, however, sets forth no allegations that the Kyowa Hakko Kirin defendants *knew* that any of their products (which, again, Dr. Pieczenik fails to name) were especially made for use in an infringement of the ‘363 patent. Dr. Pieczenik also fails to explain how the use of any such unidentified product could possibly constitute an infringement of the ‘363 patent. Accordingly, Dr. Pieczenik’s

complaint fails to state a claim for contributory infringement upon which relief can be granted.⁶

Dr. Pieczenik's complaint does not address "inducement" of infringement. 35 U.S.C. § 271(b). Even if one were to **assume** that Dr. Pieczenik intended to allege inducement, his claim would also fail as a matter of law for the same reasons his allegation of contributory infringement fails. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) ("To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they 'actively and *knowingly* aid[ed] and abett[ed] another's direct infringement.'" (citation omitted). Because Dr. Pieczenik has not identified any product or method that could possibly infringe any claim of the '363 patent (and there are none), it is impossible for him to assert that the Kyowa Hakko Kirin defendants actively induced any other unnamed party to infringe.

⁶ See, e.g., *Lucent Techs. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009); *Mallinckrodt Inc. v. E Z-EM, Inc.*, 670 F. Supp. 2d 349 (D. Del. 2009) (dismissing claim of contributory infringement because plaintiff failed to sufficiently plead that defendants had knowledge of the allegedly infringed patent); *Re'L Carriers, Inc. v. Affiliated Comp. Servs., Inc.*, No. 1:09-md-2050, 2010 U.S. Dist. LEXIS 16110, at *18-20 (S.D. Ohio Feb. 23, 2010) (dismissing claim of contributory infringement because plaintiff had not alleged that any defendant "especially designed [the allegedly infringing] product for infringing use by others, or any facts demonstrating Defendants' knowledge of such use," or "the existence of substantial noninfringing uses").

POINT II

DR. PIECZENIK'S COMPLAINT FAILS TO STATE A RICO CLAIM

Dr. Pieczenik's complaint sets forth elliptical assertions that all of the defendants -- including Kyowa Hakko Kirin defendants -- are somehow liable for violations of the RICO statute. Specifically, Dr. Pieczenik alleges that:

Upon information and belief, defendants and/or their representatives have colluded and conspired in such a fashion as to make the defendants a Racketeering Institution and Corrupt Organization in science and this organization and its members and their associates have conspired to deny Plaintiff his rightful royalties from the Pieczenik '363 patent. (D.I. 1 at ¶31)

Dr. Pieczenik's complaint, however, does not include any prayer for relief, directed to his RICO allegations. To the extent that the Court could conceivably construe Dr. Pieczenik's assertions to be a claim for relief under the civil RICO statute, 18 U.S.C. § 1964, that claim should also be dismissed in accordance with Rule 12(b)(6), Fed. R. Civ. P.

The RICO statute provides a private cause of action for injury resulting from one of four specific claims, articulated in 18 U.S.C. §§ 1962(a)-(d), involving racketeering and the collection of unlawful debts. *Banks v. Wolk*, 918 F.2d 418, 420 (3d Cir. 1990); 18 U.S.C. § 1962; 18 U.S.C. § 1964(c). Dr. Pieczenik's complaint does not cite to the RICO statute or identify which section of 18 U.S.C. § 1962 defendants have allegedly violated. Nonetheless, an element common to each of the four causes of action under the RICO statute is that the defendant engage in a pattern of

“racketeering activity.” 18 U.S.C. §§ 1962(a)-(d). *Banks*, 918 F.2d at 421 (“[N]o defendant can be liable under RICO unless he participated in two or more predicate offenses sufficient to constitute a pattern”). “Racketeering activity” is defined by statute.⁷ (Ex. J; 18 U.S.C. § 1961).

Dr. Pieczenik’s complaint does not set forth any factual allegation that the Kyowa Hakko Kirin defendants engaged in any of the statutorily-defined “racketeering activities” -- much less a “pattern of racketeering activities.”⁸ Licensing patents (D.I. 1 at ¶ 27) is simply not “racketeering activities.” (Ex. J; 18 U.S.C. § 1961). Neither is patent infringement. (*Id.*). Dr. Pieczenik’s general reference to the “defendant’s research, commercial and licensing activities” also fails to identify conduct that would qualify as a “racketeering activity.” (*Id.*). Indeed, Courts have uniformly rejected RICO claims in the context of patent matters. *See Michod v. Walker Magnetics Group, Inc.*, 115 F.R.D. 345, 347 (N.D. Ill. 1987) (“[p]atent infringement is not within the definition” of “racketeering activity”); *Semiconductor Energy Lab. Co. v.*

⁷ A copy of 35 U.S.C. § 1961(1) is attached hereto as Ex. J. That statute defines “racketeering activity” as including specified acts related to, for example: murder, kidnapping, gambling, arson, robbery, bribery, extortion, dealing in obscene matter, dealing in a controlled substance or listed chemical, bribery, counterfeiting, and theft from interstate shipment.

⁸ A RICO complaint must aver a pattern of racketeering activities -- *i.e.*, two predicate offenses that are related and pose a threat of continued activity. *Trans USA Prods. v. Howard Berger Co.*, C.A. No. 07-5924, 2008 U.S. Dist. LEXIS 25370, at *23-26 (D.N.J. Mar. 28, 2008) (dismissing RICO claim for failure to allege a pattern of racketeering activity, which requires “at least two predicate offenses” and “that the racketeering predicates are related, *and* that they amount to or pose a threat of continued criminal activity”).

Samsung Elecs. Co., 204 F.3d 1368, 1380 (Fed. Cir. 2000) (“[I]nequitable conduct before the PTO cannot qualify as an act of mail fraud or wire fraud for purposes of the predicate act requirement.”).

As a result, Dr. Pieczenik’s RICO complaint does not state a claim under 18 U.S.C. § 1964 and it should be dismissed pursuant to Rule 12(b)(6), Fed. R. Civ. P. *See Gatson v. New Jersey*, C.A. No. 09-1658, 2009 U.S. Dist. LEXIS 104154, at *36 (D.N.J. Nov. 2, 2009) (dismissing RICO claim for failure to sufficiently identify acts of racketeering or a pattern of racketeering activity).

POINT III

DR. PIECZENIK’S COMMENTS ABOUT PATENT INVALIDITY DO NOT CONSTITUTE A PROPER CLAIM

At paragraph 25 of his complaint, Dr. Pieczenik asserts that all of the defendants -- including the Kyowa Hakko Kirin defendants -- have:

[F]iled patents claiming methods, products and biological intermediates used in the display of peptide and antibody combinatorial libraries. These patents and patent applications have been filed at a later date than the original filing of the Pieczenik ‘363 Patent parent and therefore are subject to a 102(e) “snap back” prior art date. Because this ‘363 patent has issued, their patents containing claims relating to the display of combinatorial libraries are invalid. (D.I. 1 at ¶25)

Dr. Pieczenik then alleges that:

To the extent that the claims in defendant’s patents relating to the combinatorial libraries are substantially similar to claims in plaintiff’s patents, defendant’s patents are invalid. (D.I. 1 at ¶28)

Dr. Pieczenik’s “Prayer For Relief,” however, is silent on the question of invalidity.

Nonetheless, to the extent that Dr. Pieczenik's complaint could possibly be interpreted as a request for declaratory judgment that any patents owned by the Kyowa Hakko Kirin defendants are "invalid," such a claim should be dismissed for failing to state a claim on which relief can be granted in accordance with Rule 12(b)(6), Fed. R. Civ. P., as well as Rule 12(b)(1), Fed. R. Civ. P., because there is no subject matter jurisdiction for the claim.

As a preliminary matter, Dr. Pieczenik does not identify any particular patent claim owned by the Kyowa Hakko Kirin defendants that could possibly be "invalid" as a consequence of Dr. Pieczenik's '363 patent. Beyond that, there is no subject matter jurisdiction for Dr. Pieczenik to seek a declaration that any of the Kyowa Hakko Kirin defendants' patents are invalid. Indeed, declaratory judgment jurisdiction exists only if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). "[A] case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants* -- an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008). Dr. Pieczenik, as the party claiming declaratory judgment jurisdiction, bears the burden of establishing "that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has

continued since.” *See Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

Dr. Pieczenik does not allege that he is subject to any real and immediate injury or threat of injury of infringement of any patent owned by the Kyowa Hakko Kirin defendants -- and there is no factual basis to support such an allegation. The Kyowa Hakko Kirin defendants have not in any way suggested that Dr. Pieczenik infringes any of their patents. ***In fact, the Kyowa Hakko Kirin defendants do not believe that they have ever had any communication at all with Dr. Pieczenik.***

CONCLUSION

In view of the foregoing, the Kyowa Hakko Kirin defendants submit that there was no basis for Dr. Pieczenik to have filed suit against them. Accordingly, the Kyowa Hakko Kirin defendants respectfully request an Order dismissing Dr. Pieczenik's complaint with prejudice.

Respectfully submitted,

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